Remarks

A. Pending Claims

Claims 29, 31, 33-34, 38, 42, 45-46, 48-54, 56 and 60 have been rejected. Claims 29 and 56 have been amended. Claim 61 has been added. Claims 29, 31, 33-34, 38, 42, 45-46, 48-54, 56, 60 and 61 are pending.

B. Double Patenting

Claim 56 was objected to under 37 CFR 1.75 as being a substantial duplicate of claim 29. Applicant respectfully disagrees, however, to expedite prosecution claim 56 has been amended. Applicant submits that amended claim 56 is not "a substantial duplicate" of claim 29.

C. The Claims Are Not Anticipated By Heyn Pursuant To 35 U.S.C. § 102(b)

Claims 29, 42, 45-46, 48-51, 54, 56 and 60-61 were rejected pursuant to 35 U.S.C. §102 (b) as being anticipated by U.S. Patent No. 5,201,757 to Heyn et al. ("Heyn"). Applicant respectfully disagrees.

The standard for "anticipation" is one of fairly strict identity. To anticipate a claim of a patent, a single prior source must contain all the claimed essential elements. Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q.81, 91 (Fed. Cir. 1986); In re Donahue, 766 F.2d 531,226 U.S.P.Q. 619,621 (Fed. Cir. 1985).

Independent Claims 29 and 56

Independent claims 29 and 56 recite, *inter alia*:

> wherein the second conduit is movably positionable with respect to the first conduit, and wherein the distal end of the second conduit is movable in a direction toward the proximal end of the first conduit to expose at least a portion of the distal end of the stent.

With respect to claims 29 and 56, the Examiner states:

> Heyn discloses a first conduit 44, wherein at least a portion of an endoscope or bronchoscope, having at least a portion that is partially flexible, may be positionable in the first conduit during use, ... and a second conduit 20, wherein at least a portion of the first conduit is positionable in the second conduit, wherein the second conduit is configured to contain at least a portion of a stent 18 between the distal ends of the first and second conduits, and wherein the second conduit is configurable to releasably position the stent in a body lumen or air passage during use (Figure 1, col. 5, lines 15-23). The distal end of the second conduit 20 is configured to expose the stent 18 upon retracting proximally (col. 6, lines 23-27).
> (Office Action, page 3)

Applicant respectfully disagrees with the Examiner's position that Heyn teaches all of the features of claims 29 and 56. Applicant respectfully submits that the cited art does not appear to teach or suggest at least the above-cited combination of features.

Applicant discloses:

> Endoscopes are effectively utilized to deploy stents within a body cavity in a minimally invasive manner. In a conventional method, a stent is compressed to fit into the working channel of the endoscope and is delivered to the body cavity to be treated. However, storing a stent within the working channel of an endoscope causes several problems. First, there is a limitation on the size of the stent that can be compressed to fit in the working channel. Because the working channel of the endoscope is often relatively small, a large stent may not fit within the working channel. Thus, this method is not suitable for deploying large stents.
>
> Additionally, fitting a stent in the working channel often results in deformation of the stent when it is deployed into the body cavity. Since stents are made of resilient material, compression within the working channel may cause the stent to become deformed and fail to return to its original shape when released from the working channel. The more the stent gets strained, the more the deformation is likely to be.
>
> A specific example of the aforementioned problems can be seen when observing commonly used methods for positioning and deploying pulmonary stents. Currently, surgeons insert a bronchoscope into an air passageway of a patient to visually observe where a pulmonary stent needs to be positioned. They typically use a type of guide wire inserted through the bronchoscope to mark the position where they want to place the

> pulmonary stent. At this point, the bronchoscope is removed and a stent delivery system (typically associated with delivering vascular stents) is used to place the pulmonary stent using the guide wire and fluoroscopy or radioscopy to assist in positioning. This current technique requires several distinct and difficult steps and does not allow the surgeon to visually observe the actual placement of the stent. There is a need for a stent delivery system which allows for visual observation during placement of the stent and which requires fewer steps. (Specification, page 1, lines 22-40).

Heyn discloses:

> An apparatus for deploying a radially self-expanding stent includes proximal and distal sleeves respectively containing proximal and distal end portions of the stent in a reduced radius delivery configuration. The sleeves can abut one another and thus contain the entire length of the stent, or may be used in combination with an outer catheter surrounding the sleeves and containing the medial region of the stent. In either event, once the stent and sleeves are positioned at the intended fixation site, the sleeves are moved axially with respect to one another to permit radial self-expansion of the stent only over its medial region, while the sleeves continue to contain the axially outward regions of the stent. Eventually, upon sufficient movement of the sleeves axially relative to one another, the stent becomes totally free of the sleeves, resulting in radial expansion over the entire stent length. The axial relative movement of the sleeves can be controlled by two or more catheters mounted movably with respect to one another, one catheter integral with each of the sleeves. Alternative arrangements for separating the sleeves include an externally threaded inner catheter, and a dilatation balloon or membrane expandable to force the sleeves apart from one another.
> (Heyn, abstract)

Heyn also discloses:

> Distal movement of finger grip 60 moves distal sleeve 30 distally away from the more proximal sleeve 24, to deploy the distal portion of the stent. Either movement, or both in combination, will form a gap at interface 32 to allow limited radial expansion of stent 18, in particular near its center, while the proximal and distal regions remain confined between sleeves 24 and 30, respectively.
> (Heyn, col. 6, lines 27-34)

Heyn appears to disclose an apparatus for "deploying a radially self-expanding stent [that] includes proximal and distal sleeves." The "sleeves are moved axially with respect to one

another to permit radial self-expansion of the stent only over its medial region". For example, Heyn discloses, in FIG. 1, sleeves (24 and 30) that are coupled at an interface (32). Distal movement of the distal sleeve (30) away from the proximal sleeve (24) appears to cause a rupture of the interface (32) and forms a gap that allows limited radial expansion of the stent (18), see FIG. 3. It appears that the middle portion of the stent (18) expands through the gap while the ends of the stent (18) remain confined by the sleeves (24 and 30).

The Office Action notes that "Heyn teaches that the distal end of the second conduit 20 is configured to expose the stent 18 upon retracting proximally." As noted above, Heyn appears to teache that the proximal retraction of the second conduit occurs at interface 32, such that the "distal end" of the second conduit moves proximally, while the separated portion of the second conduit moves distally. Applicant submits that proximal retraction of "distal end" of the second conduit 20 exposes a middle portion of stent 18, and does not appear to teach or suggest exposing at least a portion of the distal end of the stent. Even when the stent is fully exposed, the distal end of the conduit 20 exposes the proximal end of the stent, not the distal end. The distal end of the stent 18 appears to be exposed by movement of the separated portion of second conduit 20 away from the proximal portion of the first conduit 44. In contrast, Applicant claims describe a system in which the distal end of the second conduit is movable in a direction toward the proximal end of the first conduit to expose at least a portion of the distal end of the stent, in combination with the other features of Applicant's claims.

Furthermore, Applicant discloses a stent delivery system that does not require the separation of the outer sleeve. Referring to Applicant's Fig. 1, a stent 18 is disposed on or between the distal ends of the first conduit 12 and the second conduit 14, with the second conduit containing at least a portion of stent 18. During use, second conduit 14 moves in a proximal direction away from the distal end of first conduit 12, exposing a distal end of the stent, as shown in FIG. 4. Heyn does not appear to teach or suggest a stent delivery system comprising the combination of features in Applicant's claims, including a first and second conduit and wherein the second conduit is movably positionable with respect to the first conduit, and wherein the wherein the distal end of the second conduit is movable in a direction toward the proximal end of

the first conduit to expose at least a portion of the distal end of the stent. Applicant submits Heyn does not appear to teach the combination of features in claims 29 and 56 and the claims dependent thereon.

Claim 61 recites, *inter alia,* "wherein the second conduit is movably positionable with respect to the first conduit, and wherein a distal end of the stent is initially exposed upon movement of the second conduit in a proximal direction relative to the first conduit."

As noted above, Heyn appears to teach that the middle portion of the stent 18 is initially exposed when the second conduit 20 is separated. Claim 61, however, teaches that "a distal end of the stent is initially exposed upon movement of the second conduit." Applicant respectfully submits that at least these features in combination with other features of the claim are not taught or suggested by the prior art. Accordingly, Applicant submits that claim 61 is allowable over the cited art.

Claims Depending from Claims 29 and 56

Applicant believes many of the dependent claims may be separately patentable. For example, claim 48 describes a combination of features including: "wherein at least a portion of the first conduit is configured to inhibit collapse of the first conduit upon removal of the endoscope during use." Similarly, claim 49 describes a combination of features including: "wherein at least a portion of the second conduit is configured to inhibit collapse of the second conduit." With respect to these claims, the Examiner states, "Heyn discloses at least a portion of the first and second conduits being configured to inhibit collapse of the first and second conduits upon removal of an endoscope during use (col. 5, lines 63-67 to col. 6, lines 1-5)." (Office Action, page 3). The cited portion of Heyn appears to relate to the coefficient of friction between a stent, a sleeve and/or a catheter, presumably to enable sliding of the components relative to one another. The cited portion of Heyn does not appear to even consider inhibiting the collapse of a first or second conduit. Applicant submits that at least the quoted features of claims 48 and 49, in combination with the other features of the claim, do not appear to be taught by the cited art.

Further, amended claim 60 describes a combination of features including: "wherein the second conduit is configured to retract in a proximal direction relative to the first conduit such that the stent travels out of a distal opening in the distal end of the second conduit." Applicant submits that at least the quoted features of claim 60, in combination with the other features of the claim, do not appear to be taught by the cited art.

For at least these reasons, Applicant submits claims 29, 42, 45-46, 48-49, 51, 54, 56 and 60-61 are patentable over Heyn.

D. <u>The Claims Are Not Obvious Over Heyn In View of Bui Pursuant To 35 U.S.C. § 103(a)</u>

Claim 31 was rejected under 35 U.S.C. §103(a) as obvious over Heyn in view of U.S. Patent No. 6,629,981 to Bui et al. ("Bui"). Applicant respectfully disagrees.

To reject a claim as obvious, the Examiner has the burden of establishing a *prima facie* case of obviousness. *In re Warner et al.*, 379 F.2d 1011, 154 USPQ 173, 177-178 (CCPA 1967). To establish a *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974), MPEP § 2143.03.

The Examiner states:

> Heyn discloses the claimed device except for a first lock configurable to inhibit movement of the first conduit relative to the second conduit during use, and a second lock configurable to inhibit the movement of the endoscope relative to the first conduit during use.
> (Office Action, page 4)

Applicant respectfully disagrees that Heyn discloses the claimed device. Applicant respectfully submits that claim 31 is patentable over the cited art at least for the reasons cited in Section B.

The Examiner states:

> Bui teaches a first lock 110 configurable to inhibit movement of the first conduit relative to the second conduit during use, and a second lock configurable to inhibit movement of the endoscope 124 relative to the first conduit during use (Figures 11, 15-17, and col. 9, lines 43-52 and col. 11, lines 8-19). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a first lock and a second lock, as taught by Bui, to Heyn since it was known in the art that undesirable axial movement of coaxial conduits, or sleeves, results in difficult or undesirable deployment or lack of visibility, and therefore inhibiting movement between first and second conduits facilitates deployment of the stent.
> (Office Action, page 4)

Applicant respectfully disagrees. Claim 31 describes a combination of features including, but not limited to, the feature of: "a first lock configurable to inhibit movement of the first conduit relative to the second conduit during use; and a second lock configurable to inhibit movement of the endoscope relative to the first conduit during use."

Bui discloses:

> FIG. 11 illustrates the stent delivery device after the stent 10 has been deployed. As shown, at the proximal end of the main body 102, and provided within slot 122, an endoscope 124 is locked into place against the main body 102. The endoscope 124 preferably includes a first port 126 for receiving a light source and a second port 128 for visualization. The endoscope 124, when inserted into the main body 102, preferably forms a fluid tight seal therewith, on the proximal side of the irrigation port. (Bui, column 9, lines 43-52).

Bui further discloses:

> FIGS. 15-17 illustrate the operation of the device 100 according to one embodiment of the present invention and in accordance with the delivery techniques described with respect to FIGS. 4-8 above. The endoscope 124 described above is first inserted into the proximal end of the delivery device 100. The delivery system is pushed through the urethra until the stent is located in the prostatic urethra 3. Visualization using the endoscope through the lumen of the inner catheter 14 is performed so that correct initial placement may be verified visually. Once it is verified that the distal end of the stent 10 is located at the bladder neck, the locking pin

> 110 is removed to allow movement of the sheath 16. (Bui, column 11, lines 8-19).

Bui appears to disclose retaining pin 110, which prevents the sheath 16 from moving while the pin is in place and which is "removed to allow movement of the sheath." Bui does not appear to teach or suggest a combination of features including, but not limited to, the feature of: "a second lock configurable to inhibit movement of the endoscope relative to the first conduit during use." In response to a similar argument previously presented, the Examiner states, "the endoscope 124 is locked relative to the first conduit during use (Figures 11, 15-17, and col. 9, lines 43-52 and col. 11, lines 8-19)." (Office Action, page 8). Applicant respectfully disagrees. It appears that Bui teaches that the endoscope is locked into place against the main body (102). (*see* Bui, FIG. 10). Bui does not appear to teach or suggest the endoscope is locked to inhibit movement of the endoscope relative to a first conduit during use.

Applicant submits Heyn in view of Bui does not appear to teach all of the features in claim 31.

E. <u>The Claims Are Not Obvious Over Heyn In View of Gunderson Pursuant To 35 U.S.C. § 103(a)</u>

Claims 33-34 and 53 were rejected under 35 U.S.C. §103(a) as obvious over Heyn in view of U.S. Patent No. 5,776,142 to Gunderson ("Gunderson"). Applicant respectfully disagrees.

The Examiner states:

> Heyn discloses the claimed device except for a lock configurable to inhibit movement of the first conduit relative to the second conduit during use. (Office Action, page 4)

Applicant respectfully disagrees that Heyn discloses the claimed device. Applicant respectfully submits that claims 33-34 and 53 are patentable over the cited art at least for the reasons cited in Section B.

The Examiner states:

> Gunderson teaches a lock configurable to inhibit movement of the first conduit to the second conduit during use, wherein the lock comprises a first grip 20 coupled to at least a portion of the first conduit, and a second grip 30 coupled to at least a portion of the second conduit, and one or more pins 28 coupled to the first conduit, wherein at least one of the pins is configurable to inhibit portions of the first and second conduits from moving transversely to each other wherein at least a portion of the first grip is configurable to inhibit movement of the second grip in a direction toward a proximal end of the stent delivery system beyond the portion of the first grip (Figure 1, col. 5, lines 7-16).

Applicant respectfully disagrees. Claim 33 describes a combination of features including, but not limited to, the feature of: "a lock configurable to inhibit movement of the first conduit relative to the second conduit during use, wherein the lock comprises: a first grip coupled to at least a portion of the first conduit; and a second grip coupled to at least a portion of the second conduit; wherein at least a portion of the first grip is configurable to inhibit movement of the second grip in a direction toward a proximal end of the stent delivery system beyond the portion of the first grip." Claim 34 describes a combination of features including, but not limited to, the feature of: "further comprising a lock configurable to inhibit movement of the first conduit relative to the second conduit during use, wherein the lock comprises: a first grip coupled to at least a portion of the first conduit; a second grip coupled to at least a portion of the second conduit; and one or more pins coupled to the first conduit, wherein at least one of the pins is configurable to inhibit portions of the first and second conduits from moving transversely to each other; wherein at least a portion of the first grip is configurable to inhibit movement of the second grip in a direction toward a proximal end of the stent delivery system beyond the portion of the first grip."

Gunderson discloses:

> With the two handles 20 and 30 fixedly attached to the inner and outer sheaths 40 and 50, it will be understood that rotation of the handles 20 and 30 relative to each other will cause corresponding relative rotation between the inner and outer sheaths 40 and 50. The screw portion 26 of

> handle 20 and corresponding screw receiving portion 32 of handle 30, it will also be understood that relative rotation of the handles 20 and 30 will also cause relative movement along the longitudinal axis of the device between the inner and outer sheaths 40 and 50 as will be discussed in more detail below.
> (Gunderson, column 5, lines 7-16).

Gunderson further discloses:

> The handle 20 is preferably fixedly attached to the inner sheath 40 such that rotation of the handle 20 about the longitudinal axis of the device results in corresponding rotation of the inner sheath 40. The handle 20 also preferably includes a screw portion 26 including threads 28 as shown in FIG. 1.
> The second handle 30 preferably includes a threaded opening 32 designed to receive the threads 28 of the screw portion 26 of the first handle 20. Handle 30 is fixedly attached to the outer sheath 50 such that rotation of the handle 30 about the longitudinal axis of the device results in corresponding rotation of the outer sheath 50. Handle 30 also preferably includes a release wire actuator 34 attached to the proximal end of a release wire 56 described more completely below. The actuator 34 is preferably mounted for movement along the longitudinal axis of the stent delivery device.
> (Gunderson, column 4, line 57 through column 5, line 6).

Gunderson appears to disclose a device including "threads 28 of the screw portion 26 of the first handle 20." Gunderson appears to disclose a handle 30 "fixedly attached to the outer sheath 50 such that rotation of the handle 30 about the longitudinal axis of the device results in corresponding rotation of the outer sheath 50." Accordingly, Gunderson appears to disclose a device that is configured to promote (not inhibit) both longitudinal and rotational (e.g., transverse) movement of the components relative to one another. Gunderson does not appear to teach or suggest a combination of features including, but not limited to, the feature of: "one or more pins coupled to the first conduit, wherein at least one of the pins is configurable to inhibit portions of the first and second conduits from moving transversely to each other." Applicant submits Gunderson does not appear to teach all of the features in claims 33 and 34.

Claim 53 describes a combination of features including, but not limited to, the feature of: "wherein the first conduit comprises a polymer." The features of claim 53, in combination with

the features of independent claim 29, respectively, do not appear to be taught or suggested by the prior art.

F. The Claims Are Not Obvious Over Heyn In View Of Mikus Pursuant To 35 U.S.C. § 103(a)

Claim 38 was rejected under 35 U.S.C. §103(a) as obvious over Heyn in view of U.S. Patent No. 6,093,194 to Mikus et al. ("Mikus"). Applicant respectfully disagrees.

The Exmainer states:

> Heyn discloses the claimed device except for a lock configurable to inhibit movement of the first conduit relative to the second conduit during use. (Office Action, page 6)

Applicant respectfully disagrees that Heyn discloses the claimed device. Applicant respectfully submits that claim 38 is patentable over the cited art at least for the reasons cited in Section B.

The Office Action states:

> Mikus teaches a lock configurable to inhibit movement of a first conduit 70 relative to the second conduit 75 during use, wherein the lock comprises a clamp 77, 78 in order to prevent premature proximal displacement during insertion of the conduits into the body lumen (Figure 7, col. 7, lines 54-67 to col. 8, lines 1-8). (Office Action, page 6)

Applicant respectfully disagrees. Claim 38 describes a combination of features including, but not limited to, the feature of: "a lock configurable to inhibit movement of the first conduit relative to the second conduit during use, wherein the lock comprises a clamp." The features of claim 38, in combination with the features of independent claim 29, respectively, do not appear to be taught or suggested by the prior art. Applicant submits Heyn in view of Mikus does not appear to teach all of the features in claim 38.

G. The Claims Are Not Obvious Over Heyn In View of Quiachon Pursuant To 35 U.S.C. § 103(a)

Claim 52 was rejected under 35 U.S.C. §103(a) as obvious over Heyn in view of U.S. Patent No. 5,938,623 to Quiachon ("Quiachon"). Applicant respectfully disagrees.

The Examiner states:

> Heyn discloses the claimed device except for the first conduit comprising a coiled spring.
> (Office Action, page 6)

Applicant respectfully disagrees that Heyn discloses the claimed device. Applicant respectfully submits that claim 52 is patentable over the cited art at least for the reasons cited in Section B.

The Office Action states:

> Quiachon teaches a first conduit 42 comprising a coiled spring 61 (Figure 2). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a coiled spring, as taught by Quiachon, to Heyn since it was known in the art that coiled springs used with conduits, sleeves, sheaths or catheters act as dampeners or absorb vibration along the length of a catheter.

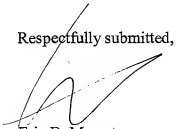
Applicant respectfully disagrees. Claim 52 describes a combination of features including, but not limited to, the feature of: "wherein the first conduit comprises a coiled spring configured to inhibit collapse of the first conduit." The features of claim 52, in combination with the features of independent claim 29, respectively, do not appear to be taught or suggested by the prior art. In contrast, the cited portion of Quiachon appear to disclose a coil (61) formed on an outer sleeve 46. *See* Quiachon, col. 5, lines 55-57). Applicant submits Heyn in view of Quiachon does not appear to teach all of the features in claim 52.

H. Conclusion

Applicant submits that the claims are in condition for allowance. Favorable reconsideration is respectfully requested.

Applicant respectfully requests a one-month extension of time. If any further extension of time is required, Applicant hereby requests the appropriate extension of time. Applicant has included a Fee Authorization Form for fees related to one-month extension of time fee. If any further fees are required, or have been overpaid, please appropriately charge, or credit, those fees to Meyertons, Hood, Kivlin, Kowert & Goetzel, P.C. Deposit Account Number 50-1505/5660-01207/EBM.

Respectfully submitted,



Eric B. Meyertons
Reg. No. 34,876

Attorney for Applicant

MEYERTONS, HOOD, KIVLIN, KOWERT & GOETZEL, P.C.
P.O. BOX 398
AUSTIN, TX 78767-0398
(512) 853-8800 (voice)
(512) 853-8801 (facsimile)

Date: Jan 28, 2009